MC ¶ 280; NC ¶ 225.[7] B. Braun recognized that manipulating AWPs to meet its competitors was "scandalous," "unethical" and "fraudulent" (although it proceeded to do it anyway). MC ¶¶ 354-55; NC ¶¶ 263-64. Baxter has confessed to the "deliberate manipulation of AWP or WAC prices [a]s a problem that we need to address." MC ¶ 301. And these are just examples.

Further still, if governments were proceeding with a tacit approval of defendants' misconduct, it would not have been necessary for the OIG, in April 2003, to issue compliance program guidance underscoring the unlawfulness of defendants' conduct. As the OIG wrote:

> Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. ***The government sets reimbursement with the expectation that the data provided are complete and accurate.*** The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act . . . if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly . . . failed to generate or report such information completely and accurately. Manufacturers may also be liable for civil money penalties under various laws, rules and regulations. Moreover, in some circumstances, inaccurate or incomplete reporting may be probative of liability under the federal anti-kickback statute.

MC ¶ 170; NC ¶ 133 (both quoting April 2003 report titled COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS (April 2003) at 11) (emphasis added).

And if governments were aware of and tacitly approved of defendants'conduct, why have some defendants recently pled ***guilty*** to criminal indictments and/or paid substantial monetary damages and penalties in settlements of governmental claims? *See, e.g.*, MC ¶¶ 617-20 (GSK); MC ¶¶ 621-27 (Bayer); MC ¶¶ 628-30 and NC ¶¶ 398-400 (AstraZeneca); MC ¶¶ 631-34 and NC ¶¶ 401-03 (Pfizer); MC ¶ 583 (TAP). And why would the recent government investigations, cited throughout the States' complaints, have been necessary if governments were aware of the

[7] Notwithstanding this acknowledgement, Aventis would indeed market the spread. *See, e.g.*, MC ¶¶ 282-88; NC ¶¶ 226-33.

fraud? And why, then, was the United States Congress "***shocked***" to learn the nature, scope and depth of the scheme as recently as the Fall of 2000? *See* NC ¶ 175; MC ¶ 212 (emphasis added). Defendants cannot answer these questions. And let us not forget the very pointed and accurate observations that Judge Young made at a hearing in the TAP criminal matter:

> This has been a gross abuse of the Medicare/Medicaid repayment system, knowing, intelligent. You have demonstrated, and it's all been confirmed in open court, and I don't want anyone forgetting about the fact that this company, not under its present management, knowingly abused the public trust in a most, and I use my words carefully, despicable way.

MC ¶ 584 (quoting *United States v. TAP Pharm. Prods., Inc.*, No. CR-01-10354-WGY (D. Mass. Dec. 6, 2001)). In light of this backdrop, it borders on the outrageous for defendants to, in essence, proclaim that "everyone knew we were committing fraud, so now we get away with it."

In any event, a determination of whether the States were on "inquiry" notice such that they should have, in the exercise of reasonable diligence, discovered the fraud earlier is a fact inquiry to be decided by the fact finder. *See, e.g., Bemis v. Estate of Bemis*, 967 P.2d 437, 440 (Nev. 1998) (the question of when a party should have discovered a cause of action "is a question of fact to be determined by the jury or trial court after a full hearing") (quoting *Millspaugh v. Millspaugh*, 611 P.2d 201, 203 (Nev. 1980)); *Siragusa v. Brown*, 971 P.2d 801, 812 (Nev. 1998) ("such factual determinations cannot be made as a matter of law") (applying Nevada RICO); *see also Young v. Lepone*, 305 F.3d 1, 9 (1st Cir. 2002) ("In the archetypical case . . . it is for the factfinder to determine whether a particular collection of data was sufficiently aposematic to place an investor on inquiry notice.") (Applying federal securities laws). Nor can defendants deny that whether a party has committed an unfair or deceptive act is a question of fact that cannot be decided at this time. *Brennan v. Carvel Corp.*, 929 F.2d 801, 813 (1st Cir. 1991) (citing *USM Corp. v. Arthur D. Little Sys.*, 28 Mass. App. Ct. 108, 124, 546 N.E.2d 888, 897 (1989)) (decided under "Massachusetts Little FTC Act"); *Frances v. Plaza Pac. Equities*, 847 P.2d 722, 724 (Nev. 1993) ("In Nevada, issues of . . . proximate cause are usually

factual issues to be determined by the trier of fact."). Defendants totally ignored all of these authorities in their reply, even though the States relied upon them in the States' opposition memorandum.

Furthermore, defendants admit that their purported governmental knowledge defense does not apply to the *parens patraie* claims, Defs. Reply at 13, but defendants ignore that, under state consumer protection laws, the appropriate standard for evaluating whether a particular type of conduct amounts to a misrepresentation is whether the conduct has the capacity to deceive and not whether the States were actually deceived. *See, e.g., Trans World Accounts, Inc. v. FTC*, 594 F.2d 212, 214 (9th Cir. 1979) (decided under FTC Act). Neither intent to deceive nor actual deception is required. *Dwyer v. J.I. Kislak Mortgage Corp.*, 13 P.3d 240, 242-43 (Wash. 2000) (Washington CPA) (citing cases), *review denied*, 29 P.3d 717 (2001); *Fraser Eng'g Co. v. Desmond*, 524 N.E.2d 110, 113 (Mass. App. Ct. 1988) (Massachusetts Act); *Glickman v. Brown*, 486 N.E.2d 737, 741 (Mass. App. Ct. 1985) (same). Thus, the State's knowledge has no bearing where actual deception is not required by the CPA. Defendants have no answer to these authorities either.[8]

In sum, defendants are invoking evidentiary issues. At the appropriate time, the evidence on these issues will be weighed, and, when that time comes, defendants' so-called "governmental knowledge" defense will fall. But here, on motion to dismiss governed by Rule 12(b)(6), such evidentiary inquiries are inappropriate.

B. Nevada Has Standing To Assert Its Nevada RICO Claims And Has Properly Alleged The Existence Of The Enterprises

1. Nevada is a "Person" under RICO

Defendants continue to maintain that Nevada is not a "person" with standing to sue for money damages under Nevada RICO. Defs. Reply at 14. After being challenged, defendants now admit that N.R.S. § 193.0205's definition of "person," which includes the State, applies.

[8] Nor do defendants contest Montana's assertion that "government knowledge" cannot be a defense to a claim under the Montana False Claims Act. *See* Joint Opp. Br. at 18-19.

Defendants new tact is to rely upon N.R.S. § 193.010, which provides that "unless the context otherwise requires, the words and terms defined in [Nevada's criminal code] have the meaning ascribed to them in those sections." Defendants now argue that the phrase "unless the context otherwise requires" means that the definitions in Nevada's criminal title, including N.R.S. § 193.0205's definition of "person," do not apply when the State seeks ***money*** damages for itself. Defs. Reply at 14.

Nothing in the Nevada statutory scheme supports defendants' interpretation that "person" should be defined differently just because money damages is a form of relief sought by Nevada. Indeed, defendants cannot overcome the fact that Nevada RICO is found within Title 15 of the Nevada criminal code governing "Crimes and ***Punishments***." (Emphasis added). The payment of money damages is just another form of "punishment." This context clearly requires that definitions applying to the criminal code generally apply to all aspects of Nevada RICO, unless Nevada RICO specifically provides an alternative definition. In this instance, Nevada RICO does not provide an alternative definition of "person." Therefore, N.R.S. § 193.010 prevails, and Nevada is a "person" under RICO for all purposes.

2. Nevada Alleges the Existence of Viable RICO Enterprises

Incorporating pages 14-17 of their brief supporting the motion to dismiss the class case (hereafter referred to as "Defs. AMCC Mem."), and pages 6-9 of their reply brief in support of that same motion ("Defs. AMCC Reply"), defendants continue to challenge Nevada's definition of the RICO enterprises. Defs. Reply at 14-15.

In ruling on the original class complaints, the Court described the Manufacturer-Publisher enterprises as "associations-in-fact comprised of each of the [drug manufacturers] and the publishers that reported their AWPs" and found that each of these enterprises consisted of one pharmaceutical company as the "hub" and "each of the [four] major publishers that reported the AWPs provided to them by the [pharmaceutical] company as the spokes." *AWP*, 263 F. Supp. 2d

at 185. The Court also found that this definition suffered from a failure of connectedness and common purpose, *id.* at 184-85, the so-called "hub-and-spoke" or "rimless wheel" problem.

In drafting its Nevada RICO count, Nevada used the Court's May 13 Order as a guidepost and eliminated the Court's concern about the "rimless wheel." Nevada alleges a separate association-in-fact enterprise consisting of a single pharmaceutical company and a single publisher (a "Manufacturer-Publisher Enterprise"). NC ¶ 448. For example, Amgen is alleged to have been a member of three separate association-in-fact Manufacturer-Publisher Enterprises: the Amgen-Thomson Medical Enterprise; the Amgen-First DataBank Enterprise; and the Amgen-Facts & Comparisons Enterprise. NC ¶ 453(a).[9] As a result, Nevada alleges 39 separate Manufacturer-Publisher Enterprises. Thus, Nevada's claim eliminates the "rimless wheel" notion that previously troubled the Court in its examination of the original class action complaint.

Nonetheless, defendants maintain that Nevada has failed to allege that the Manufacturer-Publisher Enterprises constitute ongoing organizations whose members function as continuing units and share common purposes. Defs. AMCC Mem. at 14-17; Defs. AMCC Reply at 6-9. Defendants are wrong.

a. Nevada properly alleges the each enterprise has an ongoing, continuing structure separate and apart from the racketeering activity

Contrary to defendants' assertion, *see* Defs. AMCC Reply at 7, "there is no heightened pleading standard for allegations of RICO enterprise .... 'At the pleading stage, a plaintiff typically need only identify the alleged enterprise to satisfy notice pleading requirements.'" *Grider v. Keystone Health Plan Cent., Inc.*, 2003 U.S. Dist. Lexis 16551, at *69 (E.D. Pa. Sept. 18, 2003) (quoting *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 790 (3d Cir. 1984)). Nevada has done this.

[9] The respective Manufacturer-Publisher Enterprises for the other defendants are defined in NC ¶¶ 453(a)-(m).

Nevada alleges that each of the Manufacturer-Publisher Enterprises "is an ***ongoing*** and ***continuous*** business organization consisting of both corporations and individuals," NC ¶ 449 (emphasis added), where the participants "agree[d] to a structure wherein the manufacturers made decisions as to what AWPs would be reported." NC ¶ 452. Each of the Manufacturer-Publisher Enterprises has a "systemic linkage" through "contractual relationships, financial ties, and continuing coordination of activities" including a "common communication network by which the defendant and the specific Publisher share information on a regular basis" by, typically, "a manufacturer . . . instruct[ing] a publisher to list a certain AWP." NC ¶ 450. Further, the Amended Complaint explains that each defendant sits at the top of the hierarchical decision-making structure and "made decisions as to what AWPs would be ***reported***," NC ¶ 452, and "issued instructions on how its AWPs were to be ***reported*** and each publisher accepted those instructions despite knowing of their falsity." NC ¶ 455 (emphasis added).

Thus, defendants' objections that Nevada failed to "plead a single fact" showing an ongoing and continuing business organization and decision-making structure, Defs. AMCC Mem. at 15-16, are belied by Nevada's explanation that each defendant ***reported*** fraudulent AWPs to the Publishers who then published those numbers.[10] Nevada has plainly alleged enterprises that "exhibit structural continuity which exists where there is an organizational pattern or system of authority that provides a mechanism for directing the group's affairs on a continuing, rather than an ad hoc, basis." *Manhattan Telecomms. Corp. v. DialAmerica Mktg.*, 156 F. Supp. 2d 376, 381-82 (S.D.N.Y. 2001) (cited by defendants).

Defendants also claim that "[a] RICO enterprise cannot consist of merely two separate entities engaged in a common business venture," Defs. AMCC Mem. at 17, but defendants are squarely wrong. As this Court has already recognized, "***[t]wo*** or more legal entities ***can*** form or

[10] Even though Nevada alleges the existence of an hierarchical decision-making structure headed by each defendant, the First Circuit does not even require that such an allegation be made. *See United States v. Patrick*, 248 F.3d 11, 18 (1st Cir.) (rejecting defendant "street gang" members' appeal based on district court's refusal to instruct the jury that "at a minimum, the enterprise must exhibit some sort of structure for the making of decisions, whether it be hierarchical or consensual"), *cert denied*, 534 U.S. 1043 (2001). Thus, Nevada has gone well beyond the First Circuit's enterprise pleading requirements.

be part of an association-in-fact RICO enterprise." *AWP*, 263 F. Supp. 2d 182 (emphasis in original) (citing cases). Indeed, in *United States v. London*, 66 F.3d 1227, 1243 (1st Cir. 1005) (cited by the Court here), Senior Judge Bownes noted that Defendants' proffered reading of RICO's "enterprise" element "would lead to the bizarre result that only criminals who failed to form corporate shells to aid their illicit schemes could be reached by RICO." *Id.* at 1244. Thus, the association-in-fact in *London* consisting of a bar and a check-cashing business – both legitimate businesses in their own right – sufficed as a RICO enterprise. *Id.*

The same is true here. An individual defendant and an individual Publisher are separate legal entities, each conducting their own respective businesses of (i) manufacturing and selling drugs, and (ii) publishing AWPs for drugs.[11] The enterprise was formed when – in a concerted break with past practice – the defendants began reporting fraudulent AWPs, and the Publishers began publishing them without independent verification. NC ¶ 451. Nevada has properly alleged that each Manufacturer-Publisher Enterprise had an existence separate and apart from the racketeering activity in question.[12]

The recent *Grider* decision is instructive on this issue. In that case, the plaintiff physician and her professional corporation provided medical services to about 4,000 patients who were insureds of defendant Keystone Health Plan Central, an HMO. In their civil RICO claim, plaintiffs alleged that Keystone, two entities (Capital Blue Cross and Hallmark) that controlled Keystone, and the CEOs of those three corporate entities, and "various non-parties [software

[11] The businesses conducted by each of the Publishers are considerably broader than just publishing AWPs. For instance, *First DataBank* sells a host of "healthcare knowledge" databases, various application development tools and specialty software. *See* www.firstdatabank.com. Likewise, Facts & Comparisons, Inc. publishes a wide variety of drug reference products in addition to AWP information, including drug interaction facts and formulary monographs. *See* www.factsandcomparisons.com. Thomson Medical Economics, a third Publisher, "provides nearly 170 high-quality healthcare information products and services, including magazines, directories, references, newsletters, and online services" in addition to publishing AWPs. *See* www.medec.com/html/products/index.html.

[12] Defendants rely on a footnote in the First Circuit's decision in *Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 42 (1st Cir. 1991), which dismissed a civil RICO claim because plaintiffs' complaint merely "made a ritualistic averment, in wholly conclusory terms" that defendants formed an association-in-fact enterprise. Defs. AMCC Mem. at 14. Such allegations were insufficient because plaintiffs' complaint "contained no allegations articulating how any of the [defendants] may have comprised part of an 'ongoing organization' or 'functioned as a continuing unit.'" *Id.* (quoting *Turkette,* 452 U.S. at 583). *Feinstein* is readily distinguished from this case by comparing the paltry allegations at issue in that case with the detailed allegations found in NC ¶¶ 448-52 and 454-56.

providers, claims reviewers and trade associations] together form[ed] what is styled as the 'Managed Care Enterprise', an entity which allegedly operates to defraud plaintiffs and other physicians" by wrongfully delaying and denying compensation. 2003 U.S. Dist. Lexis 16551, at *4-6, 66. In their motion to dismiss, defendants contended that plaintiffs did not "plead[] a RICO enterprise or its structure with sufficient detail." *Id.*, at *67.

Rejecting defendants' arguments, the court observed that plaintiffs had identified each entity that comprised the Managed Care Enterprise and "describe[d] how defendants allegedly use nonparty firms to further the RICO violations, employing such devices as 'common billing forms, a technology alliance and central coordination to accomplish their systematic scheme to deny, delay and diminish payments to plaintiffs.'" *Id.*, at *68-69 (record references omitted). As in this case, the defendants in *Grider* contended that "ordinary business relationships or contractual relationships do not suffice for enterprise allegations." *Id.*, at *69. The court rejected that contention, however, stating:

> [P]laintiffs allege that the relationships between the defendants and the other entities that make up the enterprise go beyond ordinary business dealings. While greater specificity with respect to structure and the interrelationship between the portions of the alleged enterprise would no doubt be desirable, ***it is uncertain how plaintiffs could accomplish this without discovery.... Plaintiffs here have identified the parties that make up the enterprise, described how these parties may be associated (through financial incentives, for example); and alleged in sufficient detail for notice pleading that the entities form a continuing unit with a common course of conduct.***

Id., at *69-70 (emphasis added).

Nevada's RICO enterprise allegations more than satisfy the applicable pleading standards, as elucidated by the *Grider* court and as set forth in other recent, persuasive district court opinions.[13] These factual allegations – which are not mere "ritualistic averments" as

[13] *See Panix Promotions, Ltd. v. Lewis*, 2002 U.S. Dist. Lexis 784, at *17 (S.D.N.Y. Jan. 17, 2002) (holding that boxer Lennox Lewis sufficiently alleged an association-in-fact enterprise consisting of his promoter, his lawyer, his manager and his financial advisor, which "evinces a 'continuity of structure'"); *R.J. Reynolds Tobacco Co. v. S K Everhart, Inc.*, 2003 U.S. Dist. Lexis 13440, at *11 (M.D.N.C. July 31, 2003) (defendants conceded that tobacco manufacturer Reynolds had properly pled an enterprise consisting of "Reynolds along with various wholesalers ... and various retailers ... [that] formed an 'association-in-fact' through their marketing relationships"; "The complaint

posited by defendants – "identif[y] the parties that make up the enterprise (each defendant and a Publisher); describe[] how these parties may be associated (through communicating AWPs and through sharing the incentives that each party to the enterprise has to preserve the AWP system); and allege[] in sufficient detail for notice pleading that the entities form a continuing unit with a common course of conduct." *Grider*, 2003 U.S. Dist. Lexis 16551, at *70. The allegations need not be lengthy and complex to meet this standard. Nevada has plainly alleged enterprises that "exhibit structural continuity which exists where there is an organizational pattern or system of authority that provides a mechanism for directing the group's affairs on a continuing, rather than an ad hoc, basis." *Manhattan Telecomms.*, 156 F. Supp. 2d at 381-82. And, these factual allegations meet the First Circuit requirement of a "common purpose" and "systematic linkage" as also evidenced by allegations of financial ties and continuing coordination. *Libertad v. Welch*, 53 F.3d 428, 444 (1st Cir. 1995).

Defendants cannot wish away these allegations. Nor can they impose a higher pleading standard that would require Nevada to have substantial "inside" knowledge of all aspects of the enterprises' operations – an impossible standard proffered by ***no*** case cited by defendants. The Court should reject defendants' challenge to the enterprises alleged by Nevada.

b. Nevada properly alleges that each enterprise has a common purpose

In detailed allegations, Nevada asserts that each Manufacturer-Publisher Enterprise has a common purpose of profiting from the publication of false and misleading AWPs. NC ¶ 449. Defendants "have this as a purpose because without the AWP scheme, they would not be able to push the spread." *Id.* And the "Publishers agree to this scheme, because if they did not, the manufacturers could easily revert to the other methods of publishing prices, or the publishers would have to independently investigate the AWP at significant expense." *Id.*[14] Indeed,

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describes that this association-in-fact had a 'unity of purpose: to promote R.J. Reynolds cigarettes to consumers in order to increase R.J. Reynolds' market share among adult smokers, while simultaneously increasing adult smoker traffic in retailers' stores.'").

[14] Thus, try as they may, defendants cannot demonstrate that the Publishers made a unilateral decision not to survey actual sales prices in the market. Defs. AMCC Reply at 9.

defendants are under no obligation to report AWPs to these publications. They could stop doing it altogether or, alternatively, report AWPs to other publications that agree "to play ball." Thus, the AMCC explains that the Publishers

> have an economic incentive to merely report the AWPs provided to them by the manufacturers, because to do otherwise would require the Publishers to spend money to extensively survey actual sales prices in the market. By simply republishing what is submitted to them by the drug manufacturers, ***the Publishers save on expenses and consequently reap greater profits.***

Id. (emphasis added).

This allegation thus provides the purpose the Court found lacking in the Manufacturer-Publisher Enterprises as originally defined by the class plaintiffs. *AWP*, 263 F. Supp. 2d at 185. Here, Nevada identifies each Publisher's joinder in the publication of inflated AWPs. NC ¶ 451. For instance, at some point prior to 1992, the Publishers in many instances obtained AWPs themselves by surveys that they conducted. Based on this survey experience, the Publishers know that the AWPs now being reported by the manufacturers are not accurate. *Id.*

The Publishers' knowledge of various government agency reports of AWP inflation also highlights their participation in the wrongdoing and the common purpose that the Publishers share with defendants. With one exception, the Publishers did not change or challenge the self-reported AWPs, but continued blindly accepting the requested AWPs, notwithstanding their knowledge of the government reports. NC ¶ 451. The one exception involves the reporting by Dey of inflated AWPs. When the State of Texas prosecuted Dey for its AWP practices, and when other states began focusing on Dey, the Publishers very recently stopped accepting Dey's reported AWPs and published a different, far lower AWP for certain Dey drugs. They withdrew from the Dey enterprise due to fear that they would be sued if they continued to publish Dey's false AWPs. This, in turn, prompted a lawsuit by Dey alleging that the Publishers were treating Dey ***differently*** than they were treating all other manufacturers. In other words, Dey was complaining of the others being allowed to continue the scheme while it could not. *Id.*

Thus, the Publishers are knowing and willing participants in the AWP Inflation Scheme and reap profits from that scheme that they otherwise would not absent the unlawful conduct. The same is true of defendants. This is precisely the type of common and shared purpose inherent in the RICO enterprise requirement, and, under the First Circuit's decision in *United States v. London*, these allegations suffice. In *London,* the criminal RICO defendant operated a bar (Heller's) and a check-cashing service (M & L). 66 F.3d at 1230. The alleged RICO enterprise was an association-in-fact between Heller's (a corporation) and M & L (a sole proprietorship). *Id.* at 1243. The government charged that London conducted the affairs of the enterprise through a pattern of racketeering activity that included illegal bookmaking and extortion. *Id.* at 1230. Notwithstanding the seemingly unrelated nature of the bar and check-cashing businesses, in affirming London's RICO conviction the First Circuit stated that "[t]he jury could have found that there was a common or shared purpose animating both the enterprise and London: doing commerce with (and thereby profiting from) bookmakers engaged in illegal gambling." *Id.* at 1244; *see also United States v. Cianci*, 210 F. Supp. 2d 71, 74-75 (D.R.I. 2002) (a legal entity need not share the criminal purposes of the individuals controlling it in order to be part of an association-in-fact enterprise).[15] Defendants and the Publishers share a similar common purpose here of simultaneously profiting from the scheme.

Defendants' reliance upon *Blue Cross v. SmithKline Beecham Clinical Labs., Inc.*, 62 F. Supp. 2d 544 (D. Conn. 1998), is misplaced. Defs. AMCC Mem. at 16. In that case, the plaintiff insurance companies and patients who paid for clinical laboratory tests conducted by SmithKline asserted civil RICO claims, contending that SmithKline had engaged in fraudulent billing practices. 62 F. Supp. 2d at 547, 549. Plaintiffs alleged a nationwide "billing network" RICO

[15] *Cianci* arose from the criminal RICO prosecution of the mayor of Providence, Rhode Island, a city official and the operator of a private business. The alleged enterprise was an association-in-fact consisting of the individual defendants, Mayor Cianci's political fundraising organization, and various city departments and agencies that defendants used to award contracts and jobs in exchange for bribes and political contributions. *Id.* at 73. Chief Judge Torres refused to dismiss the RICO indictment, even though defendants argued that the alleged association-in-fact enterprise did not have a "common purpose" because "the City and its departments were legitimate entities that did not subscribe to the defendants' alleged criminal objectives." *Id.*

enterprise consisting of SmithKline, its personnel and the hospitals, physicians, physician practice groups, and laboratories to which the fraudulent bills had been sent. *Id.* at 550. The district court found that the physicians, hospitals and laboratories that had allegedly been fooled by SmithKline's fraudulent billing scheme did not share a "common purpose" with the defendants. *Id.* at 552. The court wrote that plaintiffs' complaint was "devoid of any specific allegation that any physician, hospital, or laboratory shared [defendants'] alleged common purpose to defraud public and private health care payers." *Id.* at 553. Indeed, the plaintiffs in that case alleged that defendants' "scheme exploited the trust of both patients and payers in the physicians, as well as the trust of the physicians in [defendants]." *Id.* at 552.

In contrast, in this case Nevada specifically alleges that the Publishers were knowing and willing participants in the AWP Scheme and profited more from the scheme than they would have but for their knowing participation in the scheme. NC ¶¶ 448-51. Thus, unlike the association-in-fact enterprise at issue in *SmithKline Beecham,* the members of the Manufacturer-Publisher Enterprises here clearly shared a "common purpose."

c. Nevada properly alleges that defendants participated in the affairs of the Manufacturer-Publisher Enterprises

When a defendant is a member of the enterprise, it "participates" in the affairs of the enterprise if it "takes part in" the enterprise which, in turn, means "knowingly implementing decisions." *United States v. Oreto*, 37 F.3d 739, 750 (1st Cir. 1994). Controlling authorities maintain that liability under § 1962(c) is ***not*** limited to upper management, and that the operation or management requirement will be satisfied "by lower rung participants in the enterprise who are under the direction of upper management" provided that they at least participate in some manner in the operation and management of the enterprise. *See, e.g., Reves v. Ernst & Young*, 507 U.S. 170, 184-85 (1983); *Oreto*, 37 F.3d at 751 ("Congress intended to reach all who participate in the conduct of that enterprise, ***whether they are generals or foot soldiers***.") (emphasis added; footnote omitted).

Nevada alleges that defendants violated Nevada RICO by controlling and participating in the affairs of the Manufacturer-Publisher association-in-fact enterprises through a pattern of racketeering activity. NC ¶¶ 454-66. The allegations of participation include directly controlling the AWPs that the Publishers report and controlling the creation and distribution of marketing sales, and other materials used to inform health care providers nationwide of the profit potential of drugs. NC ¶ 454. Indeed, Nevada alleges that each defendant issued instructions on how its AWPs were to be reported, and each Publisher accepted those instructions despite knowing of their falsity. NC ¶¶ 455-56. These allegations amply satisfy the *Oreto* requirements of participation.

Here, the fact pattern in *Reves* and the cases defendants rely on do not apply, because defendants are insiders with control over the affairs of the enterprise. The *Reves* court held that the conduct or participate requirement is established when the defendant played "***some*** part in directing the enterprise's affairs." 507 U.S. at 179 (emphasis in original); *see also Aetna Cas. Sur. Co. v. P&B Autobody*, 43 F.3d 1546, 1559 (1st Cir. 1994) (the "operation or management test" established in *Reves* requires only "a degree of direction," which can be direct or indirect). The standard is even lower in cases, like here, where the defendant is itself a member of the enterprise, as opposed to an outsider. *See United States v. Owens*, 167 F.3d 739, 754 (1st Cir. 1999) ("*Reves*' [operation or management test] does not apply where a party is determined to be inside a RICO enterprise."). In upholding the RICO convictions of mere "collectors" for a loansharking ring, the First Circuit in *Oreto* carefully parsed *Reves* and emphasized that the accountants in *Reves* were not liable because they "neither made those decisions nor carried them out; in other words, the accountants were ***outside*** the chain of command through which the enterprise's affairs were conducted." *Id.* at 750 (emphasis added). The court also emphasized that "[s]pecial care is required in translating *Reves'* concern with 'horizontal' connections – focusing on the liability of an outside advisor – into the 'vertical' question of how far RICO liability may extend within the enterprise but down the organizational ladder." *Id.* Here,

defendants are classic "insiders," therefore supporting the application of the more lenient *Oreto* test.[16]

Nevada's allegations of conduct and participation clearly demonstrate that each defendant participates in the association-in-fact enterprises by knowingly implementing the decisions of the enterprises. *See Oreto*, 37 F.3d at 750; NC ¶¶ 454-66. Indeed, the allegations establish that defendants did more than just knowingly implement decisions, and that defendants in fact ***controlled*** each of their Manufacturer-Publisher Enterprises by making decisions as to what AWPs would be reported and issuing instructions on how its AWPs were to be reported. *See* NC ¶¶ 452, 455-56. The Publishers themselves have confirmed this by stating that all pricing information is supplied by the defendants without independent review. NC ¶ 131. ***And it is important to keep in mind that defendants are under no legal obligation to report AWPs or even use the Publishers but chose to do so to further their AWP Inflation Scheme through the RICO enterprise; therefore, Nevada plainly alleges control that goes well beyond the "arms-length relationships" that defendants describe***. *See* Defs. AMCC Reply at 11.

IV. SUR-REPLY TO DEFENDANT-SPECIFIC MEMORANDA

As they previously did with their opening memoranda, many defendants in their so-called "defendant-specific" reply memoranda advance common arguments. Nevada and Montana will first respond to these common issues before turning to those few remaining "individualized" issues found in the defendant-specific replies.

[16] In light of Nevada's very specific factual allegations of control ***and the First Circuit precedents cited*** and discussed above, it is surprising that Defendants continue to rely ***solely*** upon a district court outside the First Circuit, *Arrandt v. Steiner Corp.*, 2001 U.S. Dist. Lexis 11410 (N.D. Ill. Aug. 3, 2001). *See* Defs. AMCC Reply at 11. But *Arrandt* does not apply here given the contrast between the substantial allegations of control set forth by Nevada and the *Arrandt* defendant's total lack of participation in, let alone control of, the alleged enterprises. Indeed, the *Arrandt* plaintiff's complaint did not even identify by name all of the members of the alleged association-in-fact enterprise, let alone the roles that each of them played in the alleged scheme to defraud the customers. Defendants can only try to make *Arrandt* apply to this case by ignoring entire paragraphs of the Nevada Amended Complaint that explain how defendants control and participate in the respective enterprises.

A. A Generalized Scheme To Defraud Supported By Specific Allegations Directed Against Each Defendant Satisfies Rule 9(b)

Several defendants continue to assert that the States have not satisfied Rule 9(b) because the States have either not detailed why each AWP is fraudulent or set forth specific fraudulent spreads.[17] Defendants continue to ignore the Court's May 13 Order, which the States used as a guidepost in drafting their amended complaints. In doing so, the States complied with the Court's directive to list the specific drugs at issue and the allegedly fraudulent AWP. *AWP*, 263 F. Supp. 2d at 194.[18] The Appendices to each complaint contain this information, and the Court has not required any further details. Nor does Rule 9(b).

Other defendants continue to argue that the States must plead examples of wrongdoing for each specific drug targeted.[19] This is tantamount to an argument that the States must present in their complaints ***all*** of the details underpinning the full scope of each defendant's allegedly fraudulent conduct. But such details are not required by Rule 9(b), as long as the complaint alleges the "circumstances of the fraud" and "the general outline of the general scheme to defraud." *See Parke-Davis*, 147 F. Supp. 2d at 46; *Kuney Int'l, S.A. v. DiIanni*, 746 F. Supp. 234, 237 (D. Mass. 1990). The States do this, and then they provide specific examples for many of the drugs at issue. It is not necessary for the States to plead specifics for every drug and, in fact, the States could not because this information is in defendants' exclusive possession. *See Parke-Davis*, 147 F. Supp. 2d at 49 (where the Court recognized that "where the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible"); *see also id.* at 47 ("where facts underlying the fraud are 'peculiarly within the defendants' control,' a plaintiff may be excused from pleading the circumstances of

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[17] *See, e.g.,* Abbott Reply at 3 (no fraudulent AWP); Amgen Reply at 1 (no fraudulent spread); Boehringer Reply at 2 (no fraudulent spread); GSK Reply at 2-3 (no fraudulent AWP or spread); Pfizer Reply at 2 (no fraudulent AWP); Warrick Reply at 2 (no fraudulent spread).

[18] Because the State Medicaid Programs purchase all of the drugs at issue, matching purchasers with each drug is not an issue here as it was in the class action cases.

[19] AstraZeneca Reply at 2; Baxter Reply at 1-2; Bayer Reply at 2-3; GSK Reply at 1; Immunex Reply at 2-3; Novartis Reply at 1-2; Pharmacia Reply at 1; Schering Reply at 1-2; TAP Reply at 1.

the fraud with a high degree of precision") (quoting *Boston & Me. Corp. v. Hampton*, 987 F.2d 855, 866 (1st Cir. 1993)). Furthermore, the Court did not require this level of pleading detail in its May 13 Order, instead directing the plaintiffs there to identify each drug, a purchaser for each drug and the allegedly fraudulent AWP.

B. Defendants' Fraud Involving Multiple-Source Drugs Falls Squarely Within The AWP Inflation Scheme

In its opposition memorandum, the States carefully explained how generic and multiple-source drugs fit within the AWP Scheme for both drugs reimbursed by Medicare (for which the States bring co-payment claims in *parens patraie* on behalf of their residents) and by the Nevada and Montana Medicaid Programs. *See* Joint Opp. Br. at 11-15. AWP is clearly an essential ingredient of the reimbursement formula for this class of drugs. For multiple-source drugs or biologicals reimbursed under Medicare Part B, the AWP is equal to the lesser of the median AWP of all of the generic forms of the drug or biological, or the lowest AWP of the brand name product. 42 C.F.R. § 405.517. MC ¶ 187; NC ¶ 150. Under the Medicaid Program, reimbursement for multiple source drugs for which there are at least three suppliers is equal to (i) a reasonable dispensing fee, plus (ii) an amount equal to 150 percent of the lowest AWP published by *First DataBank*, *Medi-Span* or the *Red Book* (an amount called the "Federal Upper Limit" or "FUL"). 42 C.F.R. § 447.332(b); NC ¶ 151; MC ¶ 162; *see also* Mont. Admin. R. 37.86.1101(3) (incorporating FULs into the definition of "maximum allowable cost" for multiple-source drugs). In Montana, if a generic drug does not have at least three suppliers, the reimbursement amount is AWP less 15%. Mont. Admin. R. 37.86.1101(1); MC ¶ 188.

Thus, in the case of Medicare, raising an individual AWP contributes to a higher median AWP. Under Medicaid, raising an individual AWP increases the FUL if the AWP being raised is the lowest AWP published (unless there are only two suppliers of the generic drug, in which case raising the AWP increases the reimbursement amount correspondingly). MC ¶¶ 189-90; NC ¶¶ 152-53.

Highlighting the direct impact that AWP inflation has on reimbursement rates for generics (as reflected in these reimbursement formulas), the States' complaints and opposition memorandum outlined the evidence demonstrating that manipulation of AWP ***is greatest in the generic context***. *See* Joint Opp. Br. at 11-15. Indeed, some of the highest spreads of any drugs are associated with generic drugs, sometimes resulting in an AWP over 50,000% over actual costs. MC ¶ 159; NC ¶ 196. Commentators have noted that spreads are "more pronounced with generic drugs" (MC ¶ 192; NC ¶ 155); defendants' own documents demonstrate that spreads are tracked and inflated in the generic market (MC ¶ 159; NC ¶ 196); and defendant Dey has admitted that generic manufacturers are "cognizant of, and are highly attentive to, AWPs as reported … because of the ***direct relationship*** between the level of reimbursement … and the reported AWPs of these drugs." MC ¶ 200; NC ¶ 163 (emphasis added).

Dey ***now*** claims that its suit against *First DataBank*, and the allegations contained in that complaint, have no bearing here on Medicaid. Dey Reply at 2. However, Dey's allegations clearly prove otherwise. As an example, Dey recognizes that the vast majority of prescription drug transactions – as much as 85% – are covered, in whole or in part, by third-party payor reimbursement arrangements such as managed care plans ***and Medicaid***, and that both ***Medicaid*** and the private insurance systems rely on reimbursement formulas that utilize the AWP. MC ¶ 198 (citing ¶¶ 13, 14-16 of Dey Complaint.). Moreover, Dey highlighted the direct link between reported AWPs and reimbursement rates in the Medicaid Program:

> Since reimbursement to Dey's customers is, ***in Medicaid program*** in many states and in and [sic] insurance programs, ***most frequently based on the AWP as reported by the reporting services***, this arbitrary and capricious reduction by First DataBank and Medi-Span in AWP ***would result in a drastic reduction in the reimbursement*** to drug providers who choose to dispense Dey's product. Since there has not been a comparable reduction in the AWP for Dey's competitors, there would be no comparable reduction in the reimbursement the purchasers of competitive products receive. [Emphasis added.]

MC ¶ 200 (citing ¶ 50 of Dey Complaint). These are Dey's own words, not the States'.[20]

In their responses, other defendants wholly fail to address the States' explanation of how reimbursement is based on AWP in the generic context.[21] Instead, these defendants robotically recite the inaccurate incantation that competition based on increasing spreads in the generic arena cannot be possible. Defendants' argument defies the simple mathematical relationship between increasing AWPs and increasing reimbursement under the Medicare and Medicaid regulations at issue, as Dey attested to in its complaint against *First DataBank*. Furthermore, defendants' assertions run contrary to the States' allegations, *see, e.g.*, NC ¶¶ 148-63, and create an issue of fact for the jury to resolve. Defendants cannot simply win this battle on a motion to dismiss in the face of contrary allegations. They cannot win the battle on the merits, either, but that is to be decided another day.

C. In Their So-Called "Defendant-Specific Replies," Defendants Fail To Present Any Viable Arguments Supporting Dismissal Of Any Individual Defendant

1. Abbott

Abbott and TAP (which is 50 percent owned by Abbott) raise the identical argument that the States must identify competitors for all drugs in the complaints and detail the nature of the competition. Abbott Reply at 3; TAP Reply at 1-2. Abbott and TAP cite to no authority requiring such a showing, much less requiring it at this preliminary stage of the proceedings. Abbott and TAP well know what drugs compete with their own. Abbott's other arguments are largely repetitive of those set forth in its opening brief, largely ignoring the States' opposition memorandum. Because Abbott's arguments duplicate those made by other defendants, (on fraud

[20] Dey also claims that "Montana concedes that it uses a maximum allowable cost ('MAC'), which is a flat reimbursement rate, for certain multiple-source drugs." Dey Reply at 2. Montana never conceded any such thing. To the contrary, Montana explained that generic reimbursement is 150% of the FUL, or AWP less 15% if the generic drug goes not have at least three suppliers. MC ¶ 188; Joint Opp. Br. at 11. The only time MAC comes into play is in the PBM context in private reimbursement systems. *See* MC ¶¶ 193-95. But even there MAC is based on the FULs, which are, in turn, based on AWPs. *Id.*

[21] *See* Abbott Reply at 1-2; Baxter Reply at 2; Dey Reply at 1-2; Immunex Reply at 3; Pfizer Reply at 2; Pharmacia Reply at 1; TAP Reply at 1-2; Warrick Reply at 1-2.

possible in the generic arena, no competitiors identified, "government knowledge," no fraudulent AWP alleged), the States respond elsewhere in this sur-reply.

2. Amgen

Amgen continues to repeat its mantra that the allegations against it are so general as to be mere "guilt by association" with other defendants. Amgen Reply at 1. Yet the States have identified the Amgen drugs at issue (MC ¶ 234; NC ¶ 179), set forth fraudulent AWPs (*see* Appendices), explained that Amgen focuses on payor reimbursement policies (MC ¶ 239; NC ¶ 184), outlined hidden incentives Amgen provided for EPO (MC ¶¶ 243-46; NC ¶¶ 188-91), and alleged that Amgen refused to disclose to the OIG information which would have revealed secret rebates. MC ¶ 247; NC ¶ 192. Amgen also tries to explain away *Amgen, Inc. v. Scully*, 234 F. Supp. 2d 9 (D.D.C. 2002), and the 1993 OIG report, but in doing so Amgen makes factual arguments that are improper on this motion.

3. AstraZeneca

AstraZeneca continues to decry the States' inclusion of several drugs in this case even though the bulk of evidence found in the public domain to date focuses on Zoladex. AstraZeneca Reply at 2. AstraZeneca does not deny that the allegations against it with regard to Zoladex are extremely troubling, and it cannot here on this motion argue that it did not, in fact, engage in similar behavior *vis-à-vis* the additional drugs identified. As set forth above in Section IV.A., the States need not include in their complaints ***all*** of the details underpinning the full scope of AstraZeneca's allegedly fraudulent conduct because they have set forth the general outline to defraud.[22]

4. Baxter

Baxter repeats arguments it set forth in its opening brief, largely ignoring the States' opposition memorandum. Because Baxter's arguments duplicate those made by other defendants

[22] AstraZeneca claims that the Zeneca, Inc. entity was not served. The States corrected this oversight by serving Zeneca, Inc.'s registered agent in Boston on November 23, 2003.

(fraud not possible in the generic arena, no specific allegations for all drugs identified), the States respond elsewhere in this sur-reply. *See supra* at Sections IV.A and B.

5. Bayer

Bayer claims that its settlements with Montana released all claims for consumers in *parens patraie*, Bayer Reply at 1-2, but this assertion is false. The terms of the release plainly apply only to the State. This only logical because the amounts paid under the settlements were only for Medicaid Program overpayments and penalties. The recovery did not in any way represent inflated co-payments by Montanan consumers. Bayer's remaining arguments that no specifics are pled with respect to four of the identified drugs are addressed above in Section IV.A.

6. Boehringer Ingelheim

Boehringer's 9(b) arguments are addressed above in Section IV.A. As to its claim that the States must identify in the complaints all citizens on whose behalf claims are brought in *parens patraie*, Boehringer still fails to cite any authority in support of this argument. *In re Tobacco/Gov't Health Care Costs Litig.*, 83 F. Supp. 2d 125 (D.D.C. 1999), cited by Boehringer, did not hold that Guatemala must identify in its complaint all citizens sought to be protected. The footnote cited by Boehringer merely infers the unremarkable fact that Rule 9(b) applies to RICO claims. *See id.* at 135 n.8. Lastly, Boehringer Ingelheim Corporation, part of the Boehringer group of defendants used here, fails to set forth any controlling authority on point justifying its dismissal without the benefit of jurisdictional discovery.[23]

7. Braun

Braun was properly served pursuant to the First Circuit's decision in *Barrett v. Lombardi*, 239 F.3d 23, 26 (1st Cir. 2001), and Braun fails to distinguish *Barrett* in its reply. Nor does Braun persuasively argue that jurisdictional discovery is not supported. To the contrary, Braun

[23] Even if the Court were inclined to dismiss without discovery (and it should not), the dismissal should be without prejudice. If, as Boehringer claims, the issue can be resolved by reference to the Physician's Desk Reference, then dismissal should be done without prejudice.

does not "get the last word" with the DiNardo affidavit. As the States explained, the DiNardo affidavit raises more questions than it answers. Joint Opp. Br. at 37-38. The affidavit demonstrates how highly fact-specific jurisdictional inquiries can be and supports jurisdictional discovery here pursuant to *Daynard v. Ness, Motley, Loadholt, Richardson & Poole, P.A.*, 290 F.3d 42, 51 (1st Cir.), *cert. denied*, 537 U.S. 1029 (2002), which Braun did not even attempt to distinguish.

Braun also continues to insist that the deceptive trade practice claims be dismissed based on the statute of limitations, Braun Reply at 2, yet Braun failed to rebut the rule that application the discovery rule is fact inquiry for the trier of fact to decide. *See, e.g., See Siragusa*, 971 P.2d at 812; *Bemis v. Estate of Bemis*, 967 P.2d 437, 440 (Nev. 1998) (the question of when a party should have discovered a cause of action "is a question of fact to be determined by the jury or trial court after a full hearing") (quoting *Millspaugh v. Millspaugh*, 611 P.2d 201, 203 (Nev. 1980)). Indeed, Braun failed to even address *Siragusa*.

Braun's generic reimbursement argument against Montana continues to ignores the provisions of Montana's reimbursement scheme coupled with the allegations of the complaint and, for this reason, is quickly rejected. Likewise, its continuing attempts to have the *parens patriaie* claims dismissed – via argument contained solely in footnotes even though Braun has filed two briefs – is unsupported by law and ignores the long-standing authority of the Attorney General to bring claims on behalf of citizens. *See* State Def.-Specific Opp. Br. at 17-18.

8. Dey

Dey's arguments regarding generic drugs have already been addressed above at Section IV.B. As for Dey's continued attempt to engender controversy over the table appearing at paragraph 398 of Montana's complaint, *see* Dey Reply at 3, there simply is no controversy: the spread column accurately lists the calculated spreads, which Dey does not deny.

9. GSK

The arguments raised by GSK in its reply are addressed *supra* in Section IV.A.

10. Immunex

Immunex's arguments about Rule 9(b) are rebutted above in Section IV.A., and its arguments about multiple-source drugs are rebutted above in Section IV.B. With respect to Immunex's Best Price arguments, please see Section II.D. *supra.*

11. Novartis

The arguments raised by Novartis with regard to Rule 9(b) are addressed *supra* in Section IV.A. With respect to its Best Price arguments, please see Section II.D. *supra.*

12. Pfizer

Pfizer's Rule 9(b) arguments are addressed above in Section IV.A; multiple-source drugs in Section IV.B; and Best Price arguments in Section II.D.

13. Pharmacia

Pharmacia's Rule 9(b) arguments regarding no specific allegations for Celebrex are addressed above in Section IV.A; multiple-source drugs in Section IV.B; and Best Price arguments in Section II.D.

14. Schering-Plough/Warrick

Schering's Rule 9(b) argument is addressed above in Section IV.A. Warrick's reply arguments are addressed in Sections IV.A and B.

15. TAP

TAPs Rule 9(b) arguments regarding no specific allegations for Prevacid are addressed above in Section IV.A, and its arguments about multiple-source drugs are addressed in Section IV.B.[24]

[24] TAP also argues that is has not been served, TAP Reply at 2, yet TAP's counsel, Tina Tabacchi of the Jones Day Reavis & Pogue Chicago office, on or about August 6, 2003, agreed to accept service of the State complaints on behalf of TAP.

V. CONCLUSION

For the foregoing reasons, as well as those set forth in the States' joint opposition brief, the Court should deny defendants' motion to dismiss.

By /s/ Signature on file with the Court

DATED: November 25, 2003.

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CERTIFICATE OF SERVICE

I hereby certify that I, Thomas M. Sobol , an attorney, caused true and correct copies of the foregoing Plaintiffs State of Nevada's and State of Montana's Joint Surreply in Opposition to Defendants' Motion to Dismiss to be served on all counsel of record electronically, pursuant to Section D of Case Management Order No. 2., this 25th day of November 2003.

By: _____

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